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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,198	10/12/2000	Koichiro Miyake	1241.16	2149

7590 01/21/2004

Fitzpatrick Cella Harper & Scinto  
30 Rockefeller Plaza  
New York, NY 10112-3801

EXAMINER

SAIDHA, TEKCHAND

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/673,198

Applicant(s)

MIYAKE ET AL.

Examiner

Tekchand Saidha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/27/2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-25 & 29 is/are rejected.
- 7) ☐ Claim(s) 26-28 & 30-32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Final Rejection***

1. Applicant's arguments filed as per the amendment dated 10.27.2003 have been fully considered but they are not deemed to be persuasive. The reasons are discussed following the rejection(s). Acknowledgment is also made of the Information Disclosure Statement filed along with the above cited amendment.
2. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.
3. Claims 1-22 have been canceled.
4. Claims 23-32 drawn to a process of producing isoprenoid compound integrating DNA into a vector, wherein the DNA (SEQ ID NO : 31) encodes an enzyme of SEQ ID NO : 30, are pending and under consideration in this examination are pending and under consideration. **SEQ ID NO : 5 & 10 are not under consideration.**
5. ***Claim Rejections - 35 U.S.C. § 112*** (first paragraph)

***Enablement***

Claims 23-26 & 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of producing isoprenoid compound using a DNA encoding a protein having the activity to catalyze production of 2-C-methyl-D-erythritol 4-phosphate [enzyme involved is : **1-deoxy-D-xylulose 5 phosphate reductoisomerase**] from 2-C-methyl-D-erythritol 4, comprising integrating DNA into vector comprising a DNA sequence of SEQ ID NO : 31 from *Rhodobacter sphaeroides*, encoding a protein of SEQ ID NO : 30 having 1-deoxy-D-xylulose 5 phosphate reductoisomerase activity, does not reasonably provide enablement for a process of

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producing 2-C-methyl-D-erythritol 4-phosphate by culturing a vector transformed host cell containing any DNA - encoding a protein with the enzyme having 1-deoxy-D-xylulose 5 phosphate reductoisomerase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 23-26 & 29 are so broad as to encompass a process of making isoprenoid compounds using a transformed host cell comprising a DNA from any source having 1-deoxy-D-xylulose 5 phosphate reductoisomerase activity. Applicants have neither disclosed nor exemplified any of the several DNA's, many yet unidentified, encompassed by the scope of the claims. The specification only discloses 1-deoxy-D-xylulose 5 phosphate reductoisomerase DNA of SEQ ID NO : 31 from *Rhodobacter sphaeroides* and SEQ ID NO : 10. However, an amino acid sequence search and comparison between Applicants' SEQ ID NO : 30 and SEQ ID NO : 5, it was found that the 2 sequences have a sequence homology of 36.1%. However, A DNA sequence search of Applicants' SEQ ID NO : 31 [in the internal database] did not retrieve any hit with Applicants' SEQ ID NO : 10 for the first set of 30 results, indicating that the two DNA sequences have less than 10% homology amongst them. This determination is based upon the search results.

However, apart from the diverse sequences of SEQ ID NO : 31 or 10, Applicants have not disclosed other DNA molecule(s) with close similarity among or from diverse groups of plants, animals and microorganisms. Applicants have not taught or described the DNA sequence(s) or the encoding polypeptide(s) by any detailed characteristics,

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and since the disclosure is limited to the DNA and the encoded amino acid sequence of SEQ ID NO : 31 & 30 respectively; the encoding activity of 1-deoxy-D-xylulose 5 phosphate reductoisomerase, one skilled in the art cannot reasonable obtains such DNA sequences from any source.

No prior art discloses of record disclose sequences having close homology to sequence(s) of 1-deoxy-D-xylulose 5 phosphate reductoisomerase from a variety of diverse groups or sources, in a manner sufficient to provide guidance to one skilled in the art to enable the claimed invention.

While guidance is provided for how to make 1-deoxy-D-xylulose 5 phosphate reductoisomerase DNA of SEQ ID NO : 31 or 10, and in spite of the fact that the level of a skilled artisan is high, guidance to making or finding 1-deoxy-D-xylulose 5 phosphate reductoisomerase DNA or nucleic acid from any source using the sequence of SEQ ID NO : 31 or 10, or the transformants or its use in the production of isoprenoid compounds is beyond the scope of the enabling disclosure. Without sufficient guidance, determination of 1-deoxy-D-xylulose 5 phosphate reductoisomerase gene(s) from any source for integration or for mere expression into a vector and prokaryotic host cell having the desired biological function is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue in using the modified enzyme(s) in the method claimed. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Applicants Arguments :

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Applicants argue that the reformatted claims do not recite 'the hybridization language' or the language 'where one to several amino acids are deleted, added or changed..' Applicants' have overcome the Examiner's objections.

In response, the reformatted claims do address and have overcome the enablement rejection as far as these issues are concerned. However, the claims still refer to 'a process using DNA from any source', and the rejection is only maintained for this reason (See prior office action, page 8, lines 3-9) and for which no response or arguments have been filed.

6. Claims 26-28 & 30-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

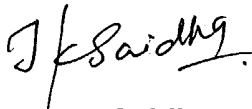
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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9. Claims drawn to specific sequences will be in a better condition for allowance.
10. During a telephone interview with the Applicants' representative, Lawrence S Perry, on January 12, 2004, allowable subject matters were discussed and Applicants were invited to amend the claims (reciting SEQ ID NO : for claims 23-25 & 29) to place them in condition for allowance. However, the discussion did not result in an agreement.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**Tekchand Saidha**  
**Primary Examiner, Art Unit 1652**  
**January 14, 2004**

**After January 21, 2004**  
**Telephone : (571) 272-0940 (Alex)**